Produktinformation

Forschungsprodukte & Biochemikalien

Zellkultur & Verbrauchsmaterial

Diagnostik & molekulare Diagnostik

Laborgeräte & Service

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immco® **DIAGNOSTICS**

A Trinity Biotech Company

Immco HEp-2 ELITE™

HEp-2/DFS70-KO IFA:
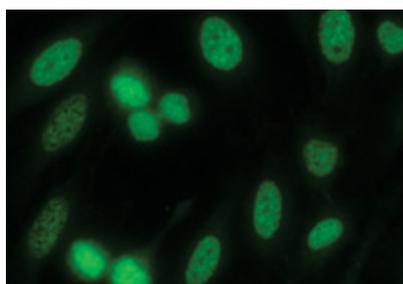## Simple ANA detection/DFS70 Ab discrimination

A new take on Antinuclear Antibodies

Anti-nuclear antibody (ANA) specificities play an important role in the diagnosis of many systemic autoimmune diseases. ANA testing by immunofluorescence technique on HEp-2 has become the standard screening method for detection of these antibodies, as recommended by the task force at the American College of Rheumatology. What makes HEp-2 a great ANA screening substrate is the variety of antibody specificities that can be detected in a single step, combined with the high clinical sensitivity and specificity inherent to this technique. Many ANA specificities have been characterized over the years that have clear association with numerous autoimmune diseases. Some antibodies, however, that can be detected on Hep-2 substrate have no known clinical association.
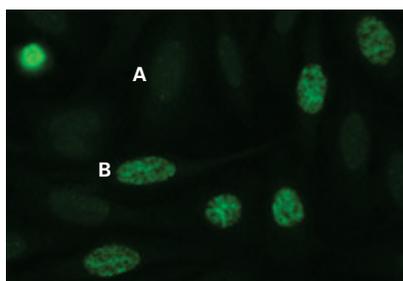

DFS70 antibodies on conventional HEp-2 Substrate

DFS70 antibodies on HEp-2/DFS70-KO Substrate

A. Engineered HEp-2
B. Conventional HEp-2

The most prevalent of these are anti-DFS70 antibodies, which are often mis-identified as clinically associated homogeneous or speckled reaction patterns. Anti-DFS70 antibodies produce a nuclear dense fine speckled immunofluorescence pattern (DSF70) on HEp-2 cells. These autoantibodies target a 70 kDa antigen also known as LEDGF (Lens Epithelium Derived Growth Factor) or *psip1* gene product. The prevalence of DFS70 antibodies in a general population ranges from 0.8 %[1] to 11%.[2] Among the ANA positive subjects over 1/3rd of the patients with positive ANA can show DFS-70 positive pattern.[3] It is of utmost importance that these reactions be differentiated in routine practice since the clinical significance of these patterns is quite different.[4]

Recognizing the challenge, Immco Diagnostics has developed a novel test to assist laboratories seeking to better discriminate anti-DFS70 antibodies from other clinically significant specificities. This HEp-2 ELITE™ substrate provides an optimal mixture of standard HEp-2 cells and engineered DFS70-KO cells.[5] Both types of cell present all classical ANA patterns with known disease association. The DFS70-KO cells inhibit DFS70 Ab reactions, providing clear differentiation of a pattern that can confound the most expert reader.

This method follows standard HEp-2 IFA protocols. There are no new reagents, no additional steps and only minimal training required to differentiate homogeneous, fine speckled, and dense fine speckled reactions in one easy screening step without the need for further confirmatory testing.

Advantages of Immco HEp-2 ELITE DFS70-KO Substrate:
- Accurate detection of classical ANA patterns and differentiation from DSF70 reactions in a single step
- Ability to reveal mixed pattern masked by DFS70 antibodies
- Low cost – eliminates the need for DFS70 Ab confirmation tests
- Optimal cell morphology and distribution
- Clear, classical ANA patterns
- Standard IFA procedure – utilizes universal Immco IFA reagents
- Minimal training required
- Easily automatable
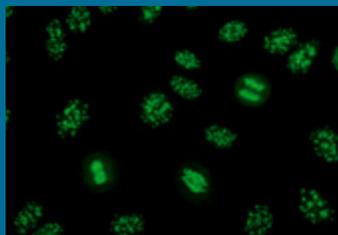
Antinuclear Antibody Detection

Simple, cost-effective differentiation of clinically important ANA reactions from DFS70

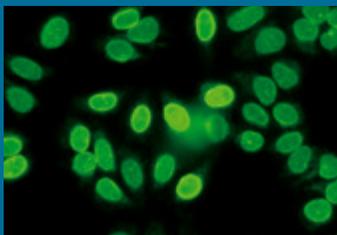|	**Homogenous**	**Speckled**	**DFS70**
HEp-2 ELITE™ HEp-2/DFS70-KO Substrate			
Standard HEp-2 Substrate			
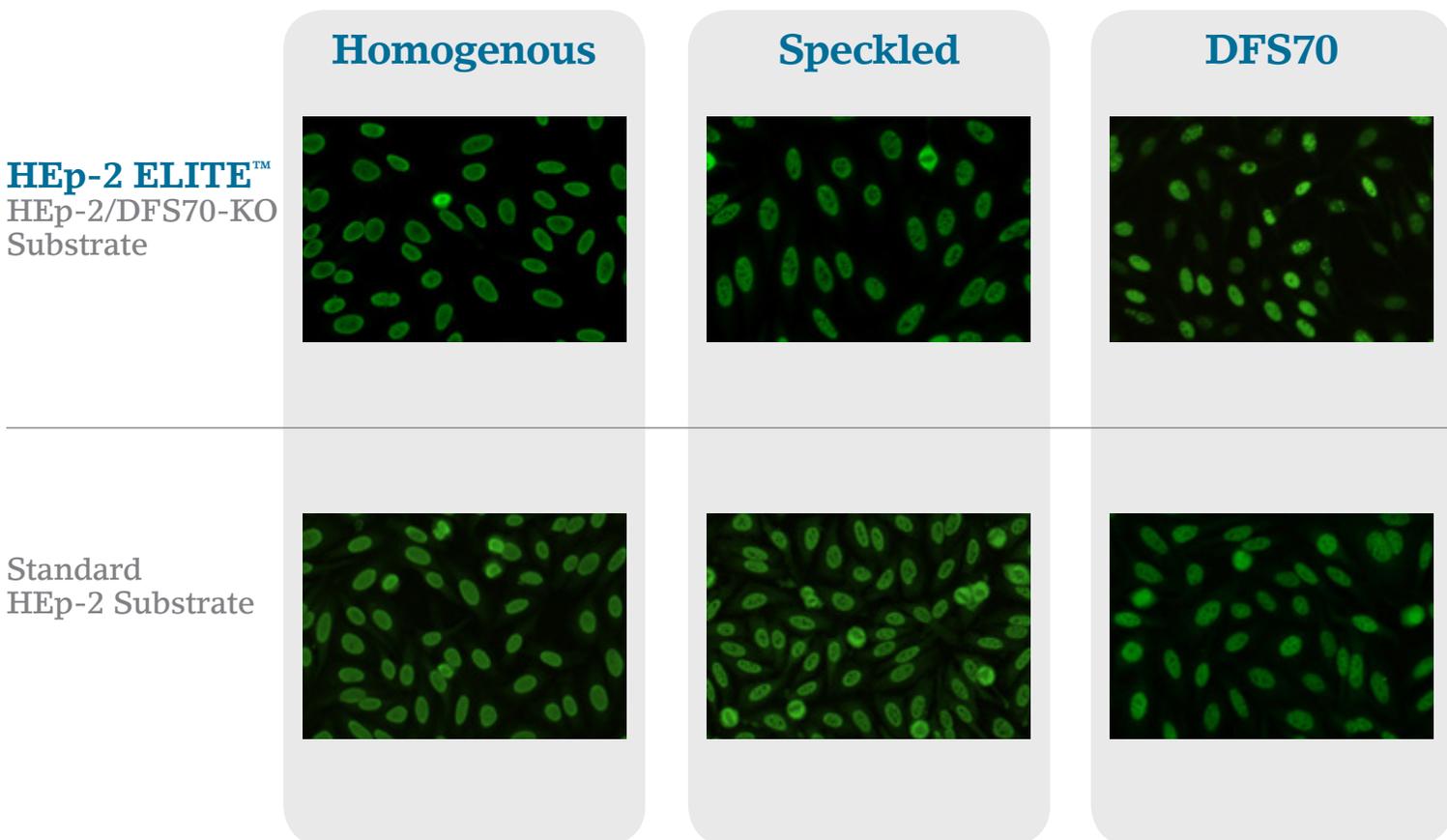
> "It is of utmost importance that the homogeneous pattern should be differentiated from the dense fine speckled (DFS) pattern in routine practice since the clinical significance of both patterns is quite different."[4]

1. Bizzaro N, Tonutti E, Tampoia M, Infantino M, Cucchiaro F, Pesente F, et al. Specific chemoluminescence and immunoasdorption tests for anti-DFS70 antibodies avoid false positive results by indirect immunofluorescence. Clinica chimica acta; international journal of clinical chemistry 2015; 451:271-7.
2. Watanabe A, Kodera M, Sugiura K, Usuda T, Tan EM, Takasaki Y, et al. Anti-DFS70 antibodies in 597 healthy hospital workers. Arthritis and rheumatism 2004; 50:892-900.
3. Dellavance A, Viana VS, Leon EP, Bonfa ES, Andrade LE, Leser PG. The clinical spectrum of antinuclear antibodies associated with the nuclear dense fine speckled immunofluorescence pattern. The Journal of rheumatology 2005; 32:2144-9.
4. Chan EK, Damoiseaux J, Carballo OG, Conrad K, de Melo Cruvinel W, Francescantonio PL, et al. Report of the First International Consensus on Standardized Nomenclature of Antinuclear Antibody HEp-2 Cell Patterns 2014-2015. Frontiers in immunology 2015; 6:412.
5. Malyavantham K, Suresh L. Improved HEp-2 substrate and impact on ANA (antinuclear antibody) screening and interpretation of anti-DFS70 (dense fine speckled) antibodies. Auto-immunity close up 2016; (In Press).
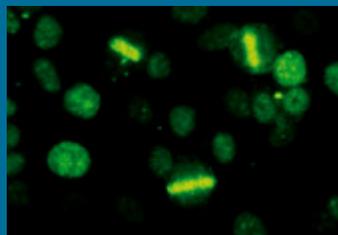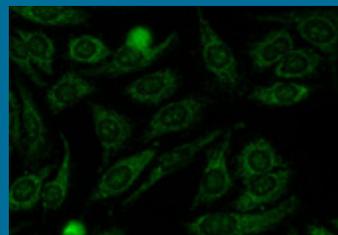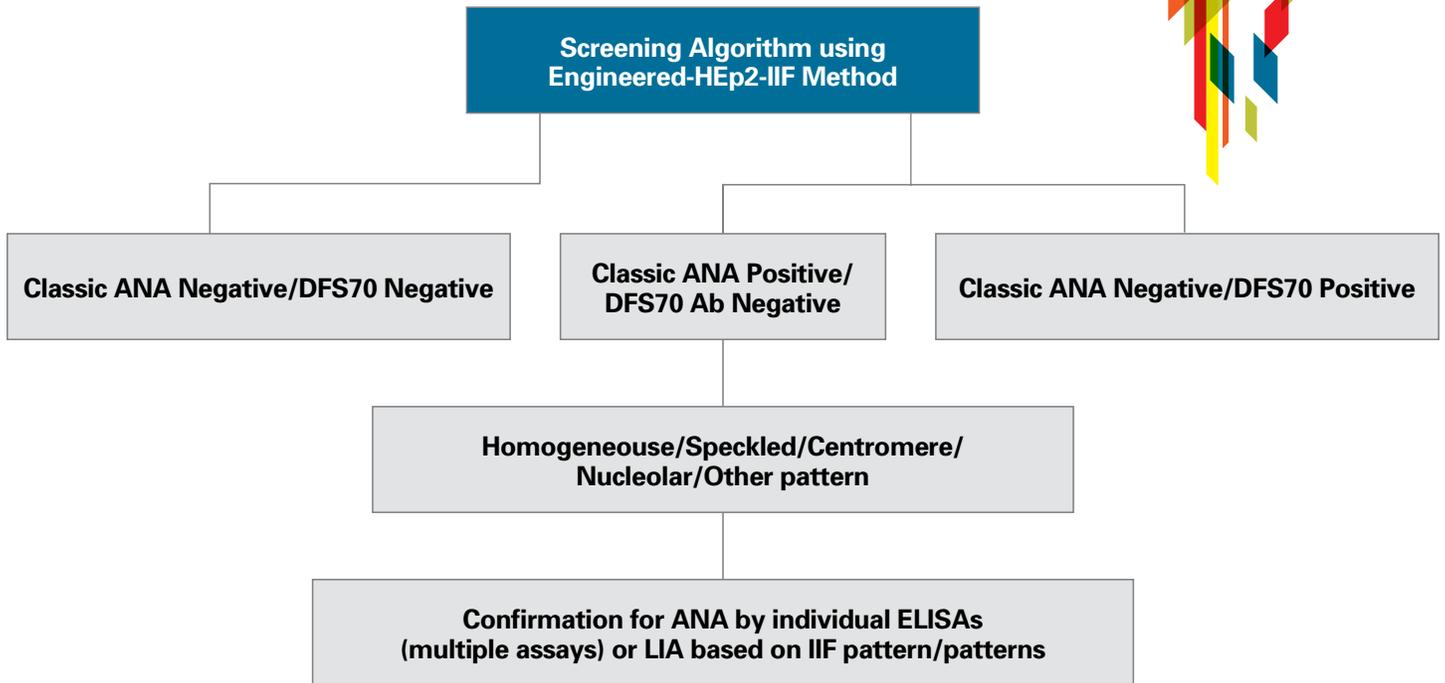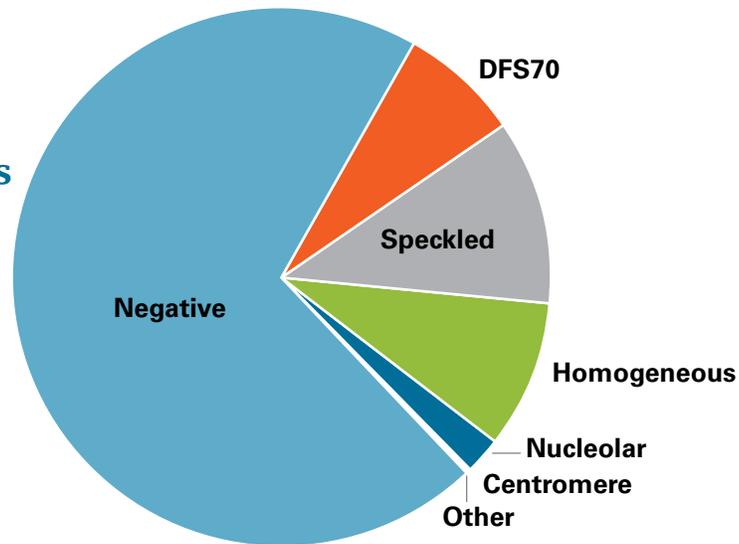
Centromere

GP-210

Midbody

Mitochondrial

on HEp-2 Cells

Screening Algorithm using Engineered-HEp2-IIF Method

- **Classic ANA Negative/DFS70 Negative**
- **Classic ANA Positive/DFS70 Ab Negative**
- **Classic ANA Negative/DFS70 Positive**

Homogeneouse/Speckled/Centromere/Nucleolar/Other pattern

Confirmation for ANA by individual ELISAs (multiple assays) or LIA based on IIF pattern/patterns

Typical Breakdown of HEp-2 Screening Results

Pie chart segments: Negative, DFS70, Speckled, Homogeneous, Nucleolar, Centromere, Other
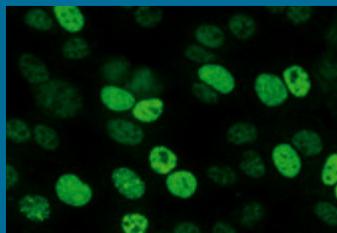
Ann Rheum Dis 2001;60:1131–1136
Rev Assoc Med Bras 2007; 53(5): 439-45
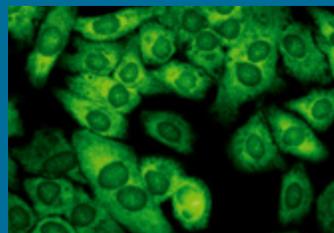Ann. N.Y. Acad. Sci. 2009; 1173: 166–173
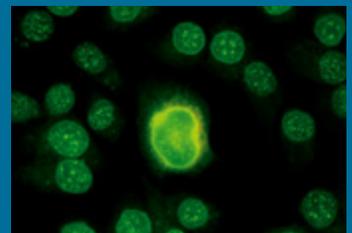
Nucleolar
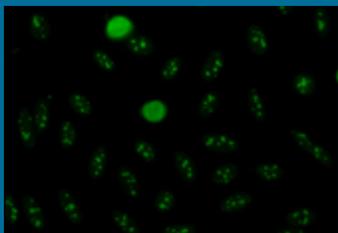
PCNA

Ribosomal P

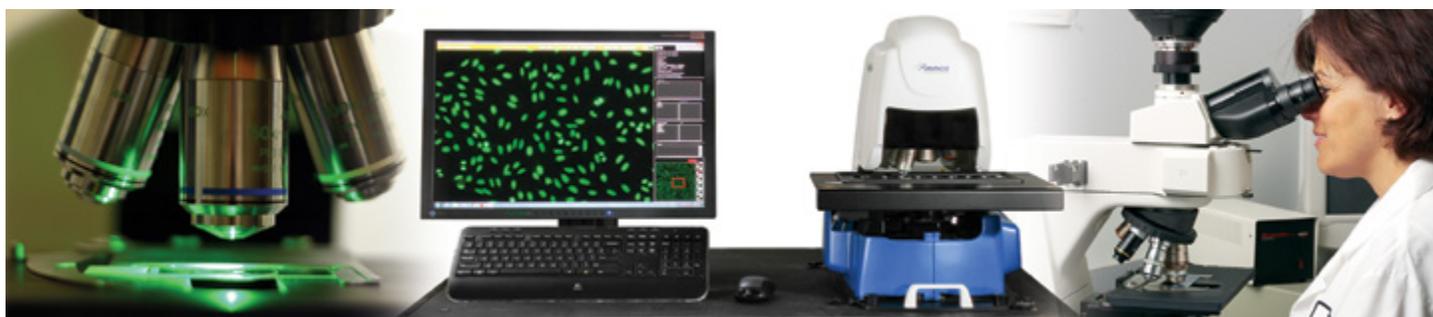**SP-100**

Diagnostic Kits and Components

A complete range of assays for diagnosis of systemic connective tissue diseases

ImmuGlo™ Immunofluorescence

IFA Kits

Code	Product Description	Determinations
1102	Autoantibody Test System 10x10 well HEp-2 slides; ANA positive control	100
1102-60	ANA HEp-2 Cell IFA 6x10 well HEp-2 slides; ANA positive control	60
1102-120	ANA HEp-2 Cell IFA 20x6 well slides, ANA positive control	120
1103	Autoantibody Test System 20x10 well HEp-2 slides; ANA positive control	200
1103-240	ANA HEp-2 Cell IFA 20x12 well HEp-2 slides; ANA positive control	240
1103-480	ANA HEp-2 Cell IFA 40x12 well HEp-2 slides; ANA positive control	480
1103-525	ANA HEp-2 Cell IFA 25 x 21 well HEp-2 slides; ANA positive control	525
1108*	HEp-2/DFS70-KO Substrate Kit 5x12 well HEp-2/DFS70-KO slides; DFS70 positive control	60
1108-120*	HEp-2/DFS70-KO Substrate Kit 10x12 well HEp-2/DFS70-KO slides; DFS70 positive control	120
1108-240*	HEp-2/DFS70-KO Substrate Kit 20x12 well HEp-2/DFS70-KO slides;	240

IFA Slides

Code	Product Description	Wells
2150	HEp-2 Cells	10
2150-6	HEp-2 Cells	6
2150-12	HEp-2 Cells	12
2150-21	HEp-2 Cells	21
2298*	HEp-2/DFS70-KO	12

IFA Components

Code	Product Description	U/M
1602	Pattern Control I Homogeneous, Speckled, Centromere, Nucleolar and Peripheral	5 x 0.5ml
2100	IgG Conjugate	5 ml
2200	Autoantibody negative control	0.5 ml
2201	ANA positive control (homogeneous)	0.5ml
2201-1	ANA low titer control (homogeneous)	0.5 ml
2202	ANA positive control (speckled)	0.5 ml
2203	ANA positive control (centromere)	0.5 ml
2204	ANA positive control (nucleolar)	0.5 ml
2205	ANA positive control (peripheral)	0.5 ml
2210	AMA Control	0.5ml
2210-1	Mitochondrial antibody low titer positive control	0.5 ml
2236	PCNA Control	0.5ml
2261	Ribosomal P Control	0.5ml
2284*	DFS70 Positive Control	0.5ml

All kits are FDA approved and CE marked for IVD use unless otherwise noted.
All Products may not be licensed for sale in Canada, please contact your Canadian distributor for more information.
*For research use only in the US.
‡Contains ImmuGlo™ anti-human IgG FITC primate adsorbed conjugate.
NOTE: All ImmuGlo™ Kits contain conjugate with Evan's Blue counterstain.
To order conjugate and Evan's Blue separately, indicate "x" after kit product code.
~Special order

For details about our products and services, please contact info@immco.com.

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